PEDIATRICS, PUBLIC HEALTH ISSUES IN

Public health and medicine represent separate and complementary approaches to the protection of health. While medicine focuses primarily on the health of individuals, public health concentrates on the health of populations. Government assumes primary responsibility for public health. Laws governing the water and food supply, controls on air pollution, legislative efforts to protect children from tobacco, mandatory immunization statutes, and the treatment of persons with sexually transmitted diseases, tuberculosis, or other communicable diseases are examples of how government may regulate environmental conditions and administer interventions that positively affect the health of a population.

Nearly every public health measure has the potential to impinge upon individual freedom. Balancing individual freedoms with the protection of a population's health represents perhaps the most important ethical issue related to public health and children. Compulsory immunization statutes illustrate these tradeoffs and the ethical issues surrounding public health interventions.

Compulsory Immunization and Children

Childhood immunization programs have been identified as one of the most effective health interventions of the twentieth century. The immunization of children effectively reduces the incidence of childhood disease. Alternatively, outbreaks of disease frequently occur when immunization rates fall (Rogers, Pilgrim, Gust, et al.). Disease prevention may be accomplished directly through the protection offered to vaccinated individuals and indirectly through a phenomenon known as *herd immunity*, in which unvaccinated individuals are protected from disease because they are surrounded by vaccinated individuals who neither contract nor spread the agent in question.

Immunization differs from most medical interventions in that it is administered to healthy individuals "to prevent diseases that often do not pose an immediate threat to the individual" (Wilson and Marcuse, p. 161). For childhood immunization programs to be successful, either parents

must willingly agree to have their children vaccinated or immunization must be coerced. While some parents may object to immunization on religious or philosophical grounds, others may believe that immunization poses a risk to their children that is not justified by its benefits.

The government's authority in the public health arena arises primarily from its constitutionally sanctioned "police power" to protect the public's health, welfare, and safety (Dover). What is the ethical basis for the exercise of these police powers? In *On Liberty*, John Stuart Mill argued that "The only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant" (p. 13).

Mill's justification for interfering with the freedom of an individual has become known as the "harm principle." Philosopher Joel Feinberg has further refined the principle by arguing that to be justified, restriction of an individual's freedom must be effective at preventing the harm in question and no option that would be less intrusive to individual liberty would be equally effective at preventing the harm.

Public health authorities may therefore be justified in interfering with parental decisions regarding immunization in two situations. First, intervention may be justified under the *parens patriae* doctrine. Under this doctrine, states have the authority to protect and care for those who cannot care for themselves and may intervene when there is evidence that parental actions or decisions are likely to harm a child. Second, intervention may be justified as an exercise of government's police powers when immunization is necessary to protect the health of the population.

Parental Refusals and the Best Interests of Children

Parents who refuse immunization on behalf of their children may have valid and important reasons for doing so. While most mandatory vaccines are effective and safe, a small possibility of adverse reactions exists. A parent might reasonably conclude that refusing the pertussis vaccine is in the best interests of a child living in a community with a high immunization rate. In such a community, the prevalence of pertussis is sufficiently low that an unimmunized child would be unlikely to contract pertussis and, therefore, could be safely spared any possible risks associated with the vaccine. In fact, it has been argued that "any successful immunization program will inevitably create a situation, as the disease becomes rare, where the individual parent's choice is at odds with society's needs" (Anderson and May, p. 415).

The parens patriae doctrine recognizes that society has an obligation to ensure that the basic needs of its most vulnerable members are met. In general, parental decisions should be accepted unless they clearly fall outside the range of what would be a reasonable decision concerning the child's best interest. In those rare cases where the decision of a parent places the child at substantial risk of serious harm, state agencies may be obligated to intervene and provide the necessary immunization over the parents' objections. For example, where a child has sustained a deep and contaminated puncture wound, the state might justifiably override a parent's refusal of tetanus immunization.

In these cases, the state acts in loco parentis, in the place of the parents. While this role of the state has been recognized as constitutionally valid in the United States, courts have closely examined such actions, showing reluctance to require medical treatment over the objection of parents "except where immediate action is necessary or where the potential for harm is rather serious" (Wing, p. 32). With the exception of an epidemic, the *parens patriae* doctrine rarely provides sufficient justification for interference with parental decisions regarding immunization with most vaccines.

Community Interests and Public Health

The harm principle justifies an exercise of the state's police powers when an individual's action puts others at risk of harm. Parents who choose not to immunize their children increase the potential for harm to other persons in three important ways (Veatch). First, immunized individuals are harmed by the cost of medical care for those who choose not to immunize their children and whose children then contract preventable disease. Second, should an unimmunized child contract disease, they pose a potential threat to other unimmunized children. Finally, even in a fully immunized population, a small percentage of vaccinated individuals will remain susceptible to disease. These individuals derive important benefit from herd immunity and may be harmed by contracting disease from those who remain unvaccinated.

A parent's refusal to vaccinate a child also raises an important question of justice referred to as the problem of "free riders" (Veatch; Rogers et al.). When immunization rates are high and disease rates low, the risks of immunization may exceed or equal the risks of contracting disease. Some parents may rationally decide not to immunize their children, taking advantage of the benefit created by the participation of others in the immunization program. These individuals act unfairly to others in the community, reaping the benefits of an immunization program without sharing any of the risks.

Compulsory immunization laws in the United States have repeatedly been upheld as a reasonable exercise of the state's police power even in the absence of an epidemic, and even where these laws conflict with the religious beliefs of individuals (Dover).

When others are placed at substantial risk of serious harm, an individual's range of choices may be restricted. However, serious harm can be averted in most situations without compulsory immunization. Under the harm principle, compulsory immunization is clearly justifiable when widespread use of an effective vaccine could limit an epidemic. In all likelihood, however, compulsory immunization would be unnecessary under such conditions since it would clearly be in the self-interest of individuals to receive the vaccine both for themselves and their children. A noncompulsory immunization program would probably bring about a result similar to a compulsory program without infringing on liberties. Indeed, immunization rates in several countries without compulsory immunization laws suggest that self-interest in combination with effective education and public relations campaigns may be sufficient to achieve protection of most individuals within a population (Noah). On the other hand, in a highly immunized population, the risk posed by a small number of unimmunized children is not significant enough to justify state action (Ross and Aspinwall).

Justice and Public Health Interventions

Most vaccines carry a small but measurable risk. At a population level, the risk of currently accepted vaccines is almost always justified by the benefit of widespread immunization to the population. With the polio vaccine, for example, one person will suffer vaccine-induced paralytic disease per million people vaccinated, as opposed to some 5,000 people developing paralytic disease per million unvaccinated people. Yet there remains the problem that an occasional individual will bear significant burden for the benefit that is provided to the rest of the population by an immunization program.

Given the unequal sharing of the burdens associated with vaccine programs, it seems fair and reasonable that those who are protected by the immunization program be asked to bear some of the burden of those few who are injured by the program (Gelfand; Anderson and May; Rogers et al.). A tax-based system of compensation for vaccine-related injuries and expenses can easily be justified.

A similar argument can be made concerning the costs of the vaccine program itself. Since all individuals in the community, even those refusing to participate through immunization, benefit from the immunization program, the costs of the immunization program should be born by the public. The full series of childhood immunizations costs more than \$500 and is not always covered by insurance. Charging individuals the cost of vaccines has a negative effect on immunization rates by offering a financial disincentive to vaccinate. At the same time, it allows "free riders" to avoid the financial costs of a program that benefits them. For those reasons, a strong argument can be made to fund immunization programs for all citizens through a tax-based system into which all citizens contribute (Diekema and Marcuse).

Public health interventions benefit all citizens. The harm principle justifies restrictions on individual liberty when individual decisions or actions put others at risk, when harm can be prevented by restricting individual liberty, and when no less restrictive alternative would be equally effective at preventing the harm. Justice requires that the burdens and benefits of public health intervention be shared equally across the population.

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SEE ALSO: Abuse, Interpersonal; Autonomy; Beneficence; Blood Transfusion; Children; Healthcare Resources, Allocation of; Health Screening and Testing in the Public Health Context; Infants; Informed Consent

BIBLIOGRAPHY

Anderson, Roy, and May, Robert. 1982. "The Logic of Vaccination." New Scientist 96(1332): 410–415.

Diekema, Douglas S., and Marcuse, Edgar K. 1998. "Ethical Issues in the Vaccination of Children." In *Primum non nocere Today*, 2nd edition, ed. G. Roberto Burgio and John D. Lantos. Amsterdam: Elsevier.

Dover, Thomas E. 1979. "An Evaluation of Immunization Regulations in Light of Religious Objections and the Developing Right of Privacy." *University of Dayton Law Review* 4(2): 401–424.

Feinberg, Joel. 1986. Harm to Self: The Moral Limits of the Criminal Law. New York: Oxford University Press.

Gelfand, Henry M. 1977. "Vaccination: An Acceptable Risk?" *Science* 195(4280): 728–29.

Mill, John Stuart. 1956. On Liberty. Indianapolis: Bobbs-Merrill.

Noah, Norman D. 1987. "Immunisation Before School Entry: Should There Be a Law?" *British Medical Journal* 294: 1270–1271.

Rogers, Anne; Pilgrim, David; Gust, Ian D.; et al. 1995. "The Pros and Cons of Immunisation." *Health Care Analysis* 3: 99–115.

Ross, Lainie Friedman, and Aspinwall, Timothy J. 1997. "Religious Exemptions to the Immunization Statutes: Balancing Public Health and Religious Freedom." *Journal of Law, Medicine & Ethics* 25: 202–209.

Veatch, Robert M. 1987. "The Ethics of Promoting Herd Immunity." Family & Community Health 10(1): 44-53.

Wilson, Christopher B., and Marcuse, Edgar K. 2001. "Vaccine Safety—Vaccine Benefits: Science and the Public's Perception." Nature Reviews Immunology 1: 160–165.

Wing, Kenneth R. 1990. *The Law and the Public's Health*. Ann Arbor, MI: Health Administration Press.

PHARMACEUTICAL INDUSTRY

In the public media and in discussions of healthcare ethics significant questions have been raised about some of the practices of the pharmaceutical industry in the early years of the twenty-first century. The increase in expenditures for medications in the United States appears to be one of the reasons for this attention. The expansion of direct-to-consumer advertising of prescription drugs, particularly on television, and the manner in which industry sales representatives relate to physicians are among the other factors that have focused attention on the industry.

Pharmaceutical companies are in the healthcare business. It therefore is not surprising that much of the interest in the ethics of the industry relates to the potential impact of company practices on the quality and cost of healthcare, access to healthcare, and the integrity of healthcare professionals. This entry discusses some of the major and recurring issues in studies of and commentaries on ethics and the pharmaceutical industry.

Relationships between Industry Representatives and Healthcare Professionals

Representatives of the pharmaceutical industry relate to healthcare professionals in a variety of ways, including personal visits with physicians, exhibits at professional meetings, industry-sponsored education on products, financial support for nonindustry educational programs, and employment of professionals as consultants. The general ethical concerns related to these relationships are whether the